

§ 211.160 General requirements.

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(b) * * *

(1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.

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■ 15. Section 211.182 is revised to read as follows:

§ 211.182 Equipment cleaning and use log.

A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under § 211.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

■ 16. Section 211.188 is amended by revising paragraph (b)(11) to read as follows:

§ 211.188 Batch production and control records.

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(b) * * *

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under § 211.68, the identification of the person checking the significant step performed by the automated equipment.

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Dated: August 22, 2008.

Jeffrey Shuren,*Associate Commissioner for Policy and Planning.*

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DEPARTMENT OF THE TREASURY**Office of Foreign Assets Control****31 CFR Part 501****Economic Sanctions Enforcement Guidelines****AGENCY:** Office of Foreign Assets Control, Treasury.**ACTION:** Interim final rule with request for comments.

SUMMARY: The Office of Foreign Assets Control (OFAC) of the U.S. Department of the Treasury is issuing this interim final rule, "Economic Sanctions Enforcement Guidelines," as enforcement guidance for persons subject to the requirements of U.S. sanctions statutes, Executive orders and regulations. This interim final rule supersedes the Economic Sanctions Enforcement Guidelines set forth in OFAC's proposed rule of January 29, 2003¹ (with the exception of the proposed Appendix to the Cuban Assets Control Regulations, 31 CFR Part 515, set forth therein) and the Economic Sanctions Enforcement Procedures for Banking Institutions set forth in OFAC's interim final rule of January 12, 2006.² These Enforcement Guidelines are published as an appendix to the Reporting, Procedures and Penalties Regulations, 31 CFR Part 501.

DATES: The interim final rule is effective September 8, 2008. Written comments may be submitted on or before November 7, 2008.

ADDRESSES: You may submit comments by any of the following methods: *Federal eRulemaking Portal:* <http://www.regulations.gov>.

Follow the instructions for submitting comments.

Fax: Attn: Request for Comments (Enforcement Guidelines) (202) 622-1657.

Mail: Attn: Request for Comments (Enforcement Guidelines), Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Instructions: All submissions received must include the agency name and the **Federal Register** Doc. number that

appears at the end of this document. Comments received will be made available to the public via [regulations.gov](http://www.regulations.gov) or upon request, without change and including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

Elton Ellison, Assistant Director, Civil Penalties, (202) 622-6140 (not a toll-free call).

SUPPLEMENTARY INFORMATION:**Electronic Availability**

This document and additional information concerning OFAC are available from OFAC's Web site (<http://www.treas.gov/ofac>) or via facsimile through a 24-hour fax-on-demand service, tel.: (202) 622-0077.

Procedural Requirements

Because this interim final rule imposes no obligations on any person, but only explains OFAC's enforcement policy and procedures based on existing substantive rules, prior notice and public comment are not required pursuant to 5 U.S.C. 553(b)(A). Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply. This interim final rule is not a significant regulatory action for purposes of Executive Order 12866.

Although a prior notice of proposed rulemaking is not required, as discussed in more detail below, OFAC is soliciting comments on this interim final rule in order to consider how it might make improvements to these Guidelines. Comments must be submitted in writing. The addresses and deadline for submitting comments appear near the beginning of this notice. OFAC will not accept comments accompanied by a request that all or part of the submission be treated confidentially because of its business proprietary nature or for any other reason. All comments received by the deadline will be a matter of public record and will be made available to the public via [regulations.gov](http://www.regulations.gov).

The collections of information related to the Reporting, Procedures and Penalties Regulations have been previously approved by the Office of Management and Budget (OMB) under control number 1505-0164. A small adjustment to that collection has been submitted to OMB in order to take into account the voluntary self-disclosure process set forth in these Guidelines. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB. This collection of

¹ 68 FR 4422-4429 (January 29, 2003).² 71 FR 1971-1976 (January 12, 2006).

information is described in subpart F of Part I, subpart G of part III and subpart B of part V of these Guidelines, which will constitute the new Appendix to part 501. The referenced subparts explain that the voluntary self-disclosure of an apparent violation to OFAC will be considered in determining the appropriate agency response to the apparent violation and, in cases where a civil monetary penalty is deemed appropriate, the base penalty amount and the proposed penalty amount. As set forth in subpart B of part V of the Guidelines, an apparent violation involving a voluntary self-disclosure will result in a base penalty amount at least 50 percent less than the base penalty amount in similar cases that do not involve a voluntary self-disclosure. This provides an incentive for persons who have or may have violated economic sanctions laws to come forward and provide OFAC information that it can use to better enforce its economic sanctions programs. The submitters who will likely seek to avail themselves of the benefits of voluntary self-disclosure are financial institutions, businesses, other entities, and individuals who find that they have or may have violated a sanctions prohibition and wish to disclose their actual or potential violation.

The estimated total annual reporting and/or recordkeeping burden: 1,250 hours. *The estimated annual burden per respondent/record keeper:* 10 hours. *Estimated number of respondents and/or record keepers:* 125. *Estimated annual frequency of responses:* Once or less, given that OFAC expects that persons who voluntarily self disclose their violations will take better care to avoid future violations. *Comments are invited on:* (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Comments concerning the above information, the accuracy of the estimated average annual burden, and suggestions for reducing this burden should be directed

to OMB, Paperwork Reduction Project, control number 1505-0164, Washington, DC 20503, with a copy to the Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Ave., NW., Washington, DC 20220. Any such comments should be submitted no later than November 7, 2008. Comments on aspects of this rule other than those involving collections of information subject to the Paperwork Reduction Act should not be sent to OMB.

Background

The primary mission of OFAC is to administer and enforce economic sanctions against targeted foreign countries and regimes, terrorists and terrorist organizations, weapons of mass destruction proliferators, narcotic traffickers, and others in furtherance of U.S. national security, foreign policy, and economic objectives. OFAC acts under Presidential national emergency powers, as well as specific legislation, to prohibit transactions and block (or "freeze") assets subject to U.S. jurisdiction. Economic sanctions are designed to deprive the target of the use of its assets and deny the target access to the U.S. financial system and the benefits of trade, transactions, and services involving U.S. markets, businesses, and individuals. These same authorities have also been used to protect assets subject to U.S. jurisdiction of countries subject to foreign occupation and to further important U.S. nonproliferation goals.

OFAC administers and enforces economic sanctions programs pursuant to Presidential and statutory authorities. OFAC is responsible for civil investigation and enforcement of economic sanctions violations committed by Subject Persons, as defined in the Guidelines. Where appropriate, OFAC may coordinate its investigative and enforcement activities with federal, state, local and/or foreign regulators and/or law enforcement agencies. Active enforcement of these programs is a crucial element in preserving and advancing the national security, foreign policy and economic objectives that underlie these initiatives. Penalties, both civil and criminal, serve as a deterrent to conduct that undermines or prevents these sanctions programs from achieving their various goals.

On January 29, 2003, OFAC published, as a proposed rule, generally applicable Economic Sanctions Enforcement Guidelines, as well as a proposed Appendix to the Cuban Assets Control Regulations (CACR) providing a schedule of proposed civil monetary

penalties for certain violations of the CACR (Cuba Penalty Schedule). Though this proposed rule was not finalized, OFAC has used the generally applicable guidelines set forth therein as a general framework for its enforcement actions and the Cuban Penalty Schedule as a framework for the imposition of civil monetary penalties for the violations of the CACR described therein. On January 12, 2006, OFAC published, as an interim final rule, Economic Sanctions Enforcement Procedures for Banking Institutions which withdrew the January 29, 2003 proposed rule to the extent that it applied to banking institutions, as defined in the interim final rule.

On October 16, 2007, the President signed into law the International Emergency Economic Powers Enhancement Act (Enhancement Act),³ substantially increasing the maximum penalties for violations of the International Emergency Economic Powers Act (IEEPA),⁴ a principal statutory authority for most OFAC sanctions programs. The increased maximum penalty amounts set forth in the Enhancement Act, as well as its application to pending or commenced cases involving apparent violations of IEEPA, prompted the development of these new Guidelines for determining an appropriate enforcement response to apparent violations of sanctions programs enforced by OFAC (as defined in the Guidelines), and, in cases involving civil monetary penalties, for determining the amount of any civil monetary penalty. The Guidelines set forth in this interim final rule supersede the enforcement procedures for banking institutions set forth in the interim final rule of January 12, 2006, which is hereby withdrawn, as well as the proposed guidelines set forth in the proposed rule of January 29, 2003, which is also hereby withdrawn, with the exception of the Cuba Penalty Schedule. (Those withdrawn enforcement procedures and guidelines continue to apply to the categories of cases set forth in OFAC's November 27, 2007 Civil Penalties—Interim Policy.) The Guidelines set forth herein are applicable to all persons subject to any of the sanctions programs administered by OFAC. As discussed in greater detail below, OFAC requests comments on this interim final rule. The Guidelines set forth in this interim final rule are not applicable to penalty or enforcement actions by other agencies based on the same underlying course of conduct, the

³Pub. Law 110-96, 121 Stat. 1011 (October 16, 2007).

⁴Pub. Law 95-223, 91 Stat. 1626 (December 28, 1977).

disposition of goods seized by Customs and Border Protection, or the release of blocked property by OFAC.

The Guidelines set forth in this interim final rule are applicable to all enforcement matters currently pending before OFAC or that will come before OFAC in the future, whether such matters fall under IEEPA or any of the other statutes pursuant to which OFAC is authorized to enforce sanctions (including, but not limited to, the Trading With the Enemy Act), with the exception of (i) those categories of cases set forth in OFAC's November 27, 2007 Civil Penalties—Interim Policy and (ii) those matters addressed in the Cuba Penalty Schedule or the Service Provider Program Circular periodically issued by OFAC pursuant to the CACR. The Guidelines reflect the factors that OFAC will consider in determining the appropriate enforcement response to an apparent violation of an OFAC sanctions program, and those factors are consistent across programs. The civil penalty provisions of the Guidelines take into account the maximum penalties available under the various statutes pursuant to which OFAC is authorized to enforce its sanctions programs.

The Guidelines reflect several changes from the 2003 proposed rule and the 2006 interim final rule. First, rather than identifying "aggravating" and "mitigating" factors, the Guidelines set forth General Factors that OFAC will consider in determining an appropriate enforcement response to an apparent violation and, if a civil monetary penalty is warranted, in establishing the amount of that penalty. The General Factors reflect the considerations that OFAC believes are most critical to a determination of appropriate agency action. The move away from "aggravating" and "mitigating" factors was motivated in part by the realization that in many cases, a particular factor could be considered either aggravating or mitigating (e.g., remedial action was considered a mitigating factor in the 2003 proposed rule, while the absence of remedial action was considered an aggravating factor). Rather than list such factors as both aggravating and mitigating factors, OFAC believes it is better practice to identify the General Factors it will consider as part of a holistic consideration of the facts and circumstances of a particular case.

Second, the Guidelines provide for the issuance of either cautionary letters or findings of violation under certain circumstances, rather than the cautionary letters and warning letters provided for in the 2003 proposed rule and the evaluative letters provided for

in the 2006 interim final rule. Cautionary letters reflect OFAC's enforcement response to an apparent violation when OFAC determines either that there is insufficient evidence to conclude that a violation has occurred or that a finding of violation is not warranted under the circumstances. A cautionary letter does not constitute a final agency determination that a violation has or has not occurred, but serves to place the Subject Person on notice that any such similar conduct in the future may result in a finding of violation or the imposition of a civil monetary penalty. Findings of violation are reserved for cases in which OFAC determines that a violation has occurred and considers it important to document the occurrence of a violation, but nevertheless concludes that the imposition of a civil monetary penalty is not the most appropriate enforcement response. Because a finding of violation constitutes a final agency determination that a violation has occurred, OFAC will afford the Subject Person an opportunity to respond to OFAC's determination. OFAC will give careful consideration to the appropriateness of issuing a cautionary letter or finding of violation in lieu of the imposition of a civil monetary penalty.

Third, in recognition of OFAC's position that the enhanced maximum civil penalties authorized by the Enhancement Act should be reserved for the most serious cases, the Guidelines distinguish between egregious and non-egregious civil monetary penalty cases. Egregious cases are defined as those representing the most serious sanctions violations, based on an analysis of all applicable General Factors, with substantial weight given to considerations of willfulness or recklessness, awareness of the conduct giving rise to an apparent violation, harm to sanctions program objectives, and the individual characteristics of the Subject Person. As described below, the Guidelines generally provide for significantly higher civil penalties for egregious cases. OFAC anticipates that the majority of enforcement cases will fall in the non-egregious category.

Fourth, in those cases in which the imposition of a civil monetary penalty is deemed appropriate, the Guidelines provide a new process for determining the penalty amount. This process involves first determining a base penalty amount. This base penalty amount is based on two primary considerations: (i) Whether the conduct, activity, or transaction giving rise to a violation is egregious or non-egregious and (ii) whether the case involves a voluntary self-disclosure by the Subject Person. As

discussed above, egregious cases are generally subject to significantly higher penalties, a result reflected in the base penalty amount for such cases. In keeping with the previous enforcement guidelines and in recognition of the importance of voluntary self-disclosures to OFAC, the existence (or lack) of a voluntary self-disclosure is a major factor in establishing the penalty amount. The base penalty amount for a case involving a voluntary self-disclosure reflects a 50 percent or more reduction from the base penalty amount that would otherwise be applicable. As set forth in greater detail in the Guidelines themselves, once a base penalty amount is calculated based on the transaction value and egregiousness/voluntary self-disclosure factors, the amount may be adjusted upward or downward based on the other General Factors set forth in the Guidelines. The resulting amount reflects OFAC's proposed civil monetary penalty.

Pre-penalty notices issued pursuant to these Guidelines will set forth the actual civil monetary penalty that OFAC proposes to impose. Thus, the pre-penalty notice will provide a Subject Person with notice of the actual penalty that the agency deems appropriate under the circumstances, rather than merely identifying the maximum possible penalty. Subject Persons will be afforded an opportunity to respond to a pre-penalty notice with arguments and/or evidence respecting the amount of the proposed penalty, which OFAC will consider prior to issuing a final penalty notice. By adopting this approach, OFAC intends to bring greater transparency to the civil penalty process and to provide more useful notice to Subject Persons that may be subject to a civil monetary penalty.

The Guidelines also address the process for settling allegations of violations.

Although this interim final rule is effective immediately, OFAC is soliciting comments for a 60-day period with a view to improving the Guidelines. Comments are requested on all aspects of the Guidelines, but are particularly sought with respect to the following:

- Are the General Factors Affecting Administrative Action the appropriate factors the agency should consider in determining the type of enforcement response to an apparent violation, and, if a civil monetary penalty is warranted, the amount of that penalty? Are there other factors that should be identified in the Guidelines? Are there factors that should be eliminated? Are there factors that should be defined with greater specificity?

- Is the definition of an egregious case appropriate?
- Are the proposed base penalty amounts appropriate for the types of cases to which they are applicable?
- Does the new penalty process, whereby the pre-penalty notice sets forth the penalty that OFAC proposes to impose, constitute an improvement on current practice? Can the process be improved in other ways?

List of Subjects in 31 CFR Part 501

Administrative practice and procedure, Banks, Banking, Insurance, Money service business, Penalties, Reporting and recordkeeping requirements, Securities.

- For the reasons set forth in the preamble, 31 CFR Part 501 is amended as follows:

PART 501—REPORTING, PROCEDURES AND PENALTIES REGULATIONS

- 1. The authority citation for Part 501 is revised to read as follows:

Authority: 8 U.S.C. 1189; 18 U.S.C. 2332d, 2339B; 19 U.S.C. 3901–3913; 21 U.S.C. 1901–1908; 22 U.S.C. 287c; 22 U.S.C. 2370(a), 6009, 6032, 7205; 28 U.S.C. 2461 note; 31 U.S.C. 321(b); 50 U.S.C. 1701–1706; 50 U.S.C. App. 1–44.

- 2. Part 501 is amended by revising Appendix A to Part 501 to read as follows:

Appendix A to Part 501—Economic Sanctions Enforcement Guidelines

Note: This appendix provides a general framework for the enforcement of all economic sanctions programs administered by the Office of Foreign Assets Control (OFAC), with the exception of those violations set forth in the proposed Appendix to the Cuban Assets Control Regulations (CACR), 31 CFR Part 515 (see 68 FR 4422, 4429 (January 29, 2003)) or in the Service Provider Program Circular periodically issued by OFAC pursuant to the CACR.

I. Definitions

A. *Apparent violation* means conduct that constitutes an actual or possible violation of U.S. economic sanctions laws, including the International Emergency Economic Powers Act (IEEPA), the Trading With the Enemy Act (TWEA), the Foreign Narcotics Kingpin Designation Act, and other statutes administered or enforced by OFAC, as well as Executive orders, regulations, orders, directives, or licenses issued pursuant thereto.

- B. *Applicable schedule amount* means:
- \$1,000 with respect to a transaction valued at less than \$1,000;
 - \$10,000 with respect to a transaction valued at \$1,000 or more but less than \$10,000;

iii. \$25,000 with respect to a transaction valued at \$10,000 or more but less than \$25,000;

iv. \$50,000 with respect to a transaction valued at \$25,000 or more but less than \$50,000;

v. \$100,000 with respect to a transaction valued at \$50,000 or more but less than \$100,000;

vi. \$170,000 with respect to a transaction valued at \$100,000 or more but less than \$170,000;

vii. \$250,000 with respect to a transaction valued at \$170,000 or more, except that where the applicable schedule amount as defined above exceeds the statutory maximum civil penalty amount applicable to an apparent violation, the applicable schedule amount shall equal such statutory maximum civil penalty amount.

C. *OFAC* means the Department of the Treasury's Office of Foreign Assets Control.

D. *Penalty* is the final civil penalty amount imposed in a Penalty Notice.

E. *Proposed penalty* is the civil penalty amount set forth in a Pre-Penalty Notice.

F. *Regulator* means any federal, state, local or foreign official or agency that has authority to license or examine an entity for compliance with federal, state, or foreign law.

G. *Subject Person* means an individual or entity subject to any of the sanctions programs administered or enforced by OFAC.

H. *Transaction value* means the dollar value of a subject transaction. In export and import cases, the transaction value generally will be the domestic value in the United States of the goods, technology, or services sought to be exported or imported into the United States, as demonstrated by commercial invoices, bills of lading, signed Customs declarations, or similar documents. In cases involving seizures by U.S. Customs and Border Protection (CBP), the transaction value generally will be the domestic value as determined by CBP. If the apparent violation at issue is a prohibited dealing in blocked property by a Subject Person, the transaction value generally will be the dollar value of the underlying transaction involved, such as the value of the property dealt in or the amount of the funds transfer that a financial institution failed to block or reject. Where the transaction value is not otherwise ascertainable, OFAC may consider the market value of the goods or services that were the subject of the transaction, the economic benefit conferred on the sanctioned party, and/or the economic benefit derived by the Subject Person from the transaction in determining transaction value. For purposes of these Guidelines, "transaction value" will not necessarily have the same meaning, nor be applied in the same manner, as that term is used for import valuation purposes at 19 CFR 152.103.

I. *Voluntary self-disclosure* means self-initiated notification to OFAC of an apparent violation by a Subject Person that has committed, or otherwise participated in, an apparent violation of a statute, Executive order, or regulation administered or enforced by OFAC, prior to the time that OFAC, or any other federal, state or local government agency or official, discovers the apparent

violation or another substantially similar apparent violation. For these purposes, "substantially similar apparent violation" means an apparent violation that is part of a series of similar apparent violations or is related to the same pattern or practice of conduct. Notification to OFAC of an apparent violation is not a voluntary self-disclosure if: a third party is required to notify OFAC of the apparent violation or a substantially similar apparent violation because a transaction was blocked or rejected by that third party (regardless of whether or when OFAC actually receives such notice from the third party and regardless of whether the Subject Person was aware of the third party's disclosure); the disclosure includes false or misleading information; the disclosure (when considered along with supplemental information provided by the Subject Person) is materially incomplete; the disclosure is not self-initiated (including when the disclosure results from a suggestion or order of a federal or state agency or official); or, when the Subject Person is an entity, the disclosure is made by an individual in a Subject Person entity without the authorization of the entity's senior management. Responding to an administrative subpoena or other inquiry from, or filing a license application with, OFAC is not a voluntary self-disclosure. In addition to notification, a voluntary self-disclosure must include, or be followed within a reasonable period of time by, a report of sufficient detail to afford a complete understanding of an apparent violation's circumstances, and should also be followed by responsiveness to any follow-up inquiries by OFAC. (As discussed further below, a Subject Person's level of cooperation with OFAC is an important factor in determining the appropriate enforcement response to an apparent violation even in the absence of a voluntary self-disclosure as defined herein; disclosure by a Subject Person generally will result in mitigation insofar as it represents cooperation with OFAC's investigation.)

II. Types of Responses to Apparent Violations

Depending on the facts and circumstances of a particular case, an OFAC investigation may lead to one or more of the following actions:

A. *No Action*. If OFAC determines that there is insufficient evidence to conclude that a violation has occurred and/or, based on an analysis of the General Factors outlined in Section III of these Guidelines, concludes that the conduct or activity does not rise to a level warranting an administrative response, then no action will be taken. In those cases in which OFAC is aware that the Subject Person has knowledge of OFAC's investigation, OFAC generally will issue a letter to the Subject Person indicating that the investigation is being closed with no administrative action being taken. A no-action determination represents a final determination as to the apparent violation, unless OFAC later learns of additional related violations or other relevant facts.

B. *Request Additional Information*. If OFAC determines that additional information regarding the apparent violation is needed, it may request further information from the

Subject Person or third parties, including through an administrative subpoena issued pursuant to 31 CFR § 501.602. In the case of an institution subject to regulation where OFAC has entered into a Memorandum of Understanding (MOU) with the Subject Person's regulator, OFAC will follow the procedures set forth in such MOU regarding consultation with the regulator. Even in the absence of an MOU, OFAC may seek relevant information about a regulated institution and/or the conduct or activity constituting the apparent violation from the institution's federal, state, or foreign regulator. Upon receipt of information determined to be sufficient to assess the apparent violation, OFAC will decide, based on an analysis of the General Factors outlined in Section III of these Guidelines, whether to pursue further enforcement action or whether some other response to the apparent violation is appropriate.

C. Cautionary Letter: If OFAC determines that there is insufficient evidence to conclude that a violation has occurred or that a finding of violation is not warranted under the circumstances, but believes that the underlying conduct could lead to a violation in other circumstances and/or that a Subject Person does not appear to be exercising due diligence in assuring compliance with the statutes, Executive orders, and regulations that OFAC enforces, OFAC may issue a cautionary letter that conveys its concerns about the underlying conduct and/or the Subject Person's OFAC compliance policies, practices and/or procedures. A cautionary letter represents a final enforcement response to the apparent violation, unless OFAC later learns of additional related violations or other relevant facts, but does not constitute a final agency determination as to whether a violation has occurred.

D. Finding of Violation: If OFAC determines that a violation has occurred and considers it important to document the occurrence of a violation and, based on an analysis of the General Factors outlined in Section III of these Guidelines, concludes that the Subject Person's conduct warrants an administrative response but that a civil monetary penalty is not the most appropriate response, OFAC may issue a finding of violation that identifies the violation, conveys OFAC's concerns about the violation and/or the Subject Person's OFAC compliance policies, practices and/or procedures, and/or identifies the need for further compliance steps to be taken. A finding of violation represents a final enforcement response to the violation, unless OFAC later learns of additional related violations or other relevant facts, and constitutes a final agency determination that a violation has occurred. A finding of violation will afford the Subject Person an opportunity to respond to OFAC's determination that a violation has occurred.

E. Civil Monetary Penalty. If OFAC determines that a violation has occurred and, based on an analysis of the General Factors outlined in Section III of these Guidelines, concludes that the Subject Person's conduct warrants the imposition of a monetary penalty, OFAC may impose a civil monetary penalty. Civil monetary penalty amounts will

be determined as discussed in Section V of these Guidelines. The imposition of a civil monetary penalty constitutes a final agency determination that a violation has occurred and represents a final civil enforcement response to the violation.

F. Criminal Referral. In appropriate circumstances, OFAC may refer the matter to appropriate law enforcement agencies for criminal investigation and/or prosecution. Apparent sanctions violations that OFAC has referred for criminal investigation and/or prosecution also may be subject to OFAC civil penalty or other administrative action.

G. Other Administrative Actions. In addition to or in lieu of other administrative actions, OFAC may also take the following administrative actions in response to an apparent violation:

1. **License Denial, Suspension, Modification, or Revocation.** OFAC authorizations to engage in a transaction (including the release of blocked funds) pursuant to a general or specific license may be withheld, denied, suspended, modified, or revoked in response to an apparent violation.

2. **Cease and Desist Order.** OFAC may order the Subject Person to cease and desist from conduct or activities that are prohibited by any of the sanctions programs enforced by OFAC when OFAC has reason to believe that a Subject Person has engaged in such conduct or activities and/or that such conduct or activities are ongoing or may recur.

III. General Factors Affecting Administrative Action

The type of enforcement action undertaken by OFAC will depend on the nature of the apparent violation and the harm caused to the relevant sanctions program and its objectives. As a general matter, OFAC will consider some or all of the following General Factors in determining the appropriate administrative action in response to an apparent violation of U.S. sanctions by a Subject Person, and, where a civil monetary penalty is imposed, in determining the appropriate amount of any such penalty:

A. Willful or Reckless Violation of Law: a Subject Person's willfulness or recklessness in violating, attempting to violate, conspiring to violate, or causing a violation of the law. Generally, to the extent the conduct, activity or transaction at issue is the result of willful misconduct or a deliberate intent to violate, attempt to violate, conspire to violate, or cause a violation of the law, the OFAC enforcement response will be stronger. Among the factors OFAC may consider in evaluating willfulness or recklessness are:

1. **Willfulness.** Was the conduct at issue the result of a decision to take action with the knowledge that such action would constitute a violation of U.S. law? Did the Subject Person know that the underlying conduct constituted, or likely constituted, a violation of U.S. law at the time of the conduct?

2. **Recklessness.** Did the Subject Person demonstrate reckless disregard for U.S. sanctions requirements or otherwise fail to exercise a minimal degree of caution or care in avoiding conduct, activities or transactions that led to the apparent violation? Were there warning signs that should have alerted the

Subject Person that an action or failure to act would lead to an apparent violation?

3. **Concealment.** Was there an effort by the Subject Person to hide or purposely obfuscate its conduct, activities or transactions in order to mislead OFAC, federal, state or foreign regulators, or other parties involved in the transaction/conduct about an apparent violation?

4. **Pattern of Misconduct.** Was the apparent violation the result of a pattern or practice of conduct or was it relatively isolated and atypical in nature?

5. **Prior Notice.** Was the Subject Person on notice, or should it reasonably have been on notice, that the conduct at issue, or similar conduct, constituted a violation of U.S. law?

6. **Management Involvement.** In cases of entities, at what level within the organization did the willful or reckless misconduct occur? Were supervisory or managerial level staff aware, or should they reasonably have been aware, of the willful or reckless misconduct?

B. Awareness of Conduct at Issue: The Subject Person's awareness of the conduct, activity or transaction giving rise to the apparent violation. Generally, the greater a Subject Person's actual knowledge of, or reason to know about, the conduct, activity, or transaction constituting an apparent violation, the stronger the OFAC enforcement response will be. In the case of a corporation, awareness will focus on supervisory or managerial level staff in the business unit at issue, as well as other senior officers and managers. Among the factors OFAC may consider in evaluating the Subject Person's awareness of the conduct at issue are:

1. **Actual Knowledge.** Did the Subject Person have actual knowledge that the conduct, activity, or transaction giving rise to an apparent violation took place? Was the conduct, activity, or transaction part of a business process, structure or arrangement that was designed or implemented with the intent to prevent or shield the Subject Person from having such actual knowledge, or was the conduct, activity, or transaction part of a business process, structure or arrangement implemented for other legitimate reasons that made it difficult or impossible for the Subject Person to have actual knowledge?

2. **Reason to Know.** If the Subject Person did not have actual knowledge that the conduct, activity, or transaction took place, did the Subject Person have reason to know, or should the Subject Person reasonably have known, based on all readily available information and with the exercise of reasonable due diligence, that the conduct, activity, or transaction would or might take place?

3. **Management Involvement.** In the case of an entity, was the conduct, activity or transaction undertaken with the explicit or implicit knowledge of senior management, or was the conduct, activity, or transaction undertaken by personnel outside the knowledge of senior management? If the apparent violation was undertaken without the knowledge of senior management, was there oversight intended to detect and prevent violations, or did the lack of knowledge by senior management result from disregard for its responsibility to comply with applicable sanctions laws?

C. Harm to Sanctions Program Objectives: The actual or potential harm to sanctions program objectives caused by the conduct, activities, or transactions giving rise to the apparent violation. Among the factors OFAC may consider in evaluating the harm to sanctions program objectives are:

1. *Economic or Other Benefit to the Sanctioned Individual, Entity, or Country:* The economic or other benefit conferred or attempted to be conferred to sanctioned individuals, entities, or countries as a result of an apparent violation, including the number, size, and impact of the transactions or incidents constituting an apparent violation(s), the length of time over which they occurred, and the nature of the economic or other benefit conferred. OFAC may also consider the causal link between the Subject Person's conduct and the economic benefit conferred or attempted to be conferred.

2. *Implications for U.S. Policy:* The effect that the circumstances of the apparent violation had on the integrity of the U.S. sanctions program and the related policy objectives involved.

3. *License Eligibility:* Whether the conduct constituting the apparent violation likely would have been licensed by OFAC under existing licensing policy.

4. *Humanitarian activity:* Whether the conduct at issue was in support of a humanitarian activity.

D. Individual Characteristics: The particular circumstances and characteristics of a Subject Person. Among the factors OFAC may consider in evaluating individual characteristics are:

1. *Commercial Sophistication:* The commercial sophistication and experience of the Subject Person. Is the Subject Person an individual or an entity? If an individual, was the transaction constituting the apparent violation conducted for personal or business reasons?

2. *Size of Operations and Financial Condition:* The size of a Subject Person's business operations and overall financial condition may be considered, where such information is available and relevant. Qualification of the Subject Person as a small business or organization for the purposes of the Small Business Regulatory Enforcement Fairness Act, as determined by reference to the applicable regulations of the Small Business Administration, may also be considered.

3. *Volume of Transactions:* The total volume of transactions undertaken by the Subject Person on an annual basis, with attention given to the apparent violations as compared with the total volume.

4. *Sanctions Violation History:* The Subject Person's history of sanctions violations, including OFAC's issuance of prior findings of violations or cautionary, warning or evaluative letters, or other administrative actions.

E. Compliance Program: The existence and nature of a Subject Person's OFAC compliance program at the time of the apparent violation, where relevant. In the case of an institution subject to regulation where OFAC has entered into a Memorandum of Understanding (MOU) with

the Subject Person's regulator, OFAC will follow the procedures set forth in such MOU regarding consultation with the regulator with regard to the quality and effectiveness of the Subject Person's compliance program. Even in the absence of an MOU, OFAC may take into consideration the views of federal, state, or foreign regulators, where relevant.

F. Remedial Response: The Subject Person's corrective action taken in response to the apparent violation. Among the factors OFAC may consider in evaluating the remedial response are:

1. The steps taken by the Subject Person upon learning of the apparent violation. Did the Subject Person immediately stop the conduct at issue?

2. In the case of an entity, the processes followed to resolve issues related to the apparent violation. Did the Subject Person discover necessary information to ascertain the causes and extent of the apparent violation, fully and expeditiously? Where applicable, were the Audit Committee and the Board of Directors fully informed? If so, when?

3. In the case of an entity, whether the Subject Person adopted new and more effective internal controls and procedures to prevent a recurrence of the apparent violation. If the Subject Person did not have an OFAC compliance program in place at the time of the apparent violation, did it implement one upon discovery or notification of the violations? If it did have an OFAC compliance program, did it take appropriate steps to enhance the program to prevent the recurrence of similar violations? Did the entity provide the individual(s) responsible for the apparent violation with additional training, and/or take other appropriate action, to ensure that similar violations do not occur in the future?

4. Where applicable, whether the Subject Person undertook a thorough review to identify other possible violations.

G. Cooperation with OFAC: The nature and extent of the Subject Person's cooperation with OFAC. Among the factors OFAC may consider in evaluating cooperation with OFAC are:

1. Did the Subject Person voluntarily self-disclose the apparent violation to OFAC?

2. Did the Subject Person provide OFAC with all relevant information regarding an apparent violation (whether or not voluntarily self-disclosed)?

3. Did the Subject Person research and disclose to OFAC relevant information regarding any other apparent violations caused by the same course of conduct?

4. Was information provided voluntarily or in response to an administrative subpoena?

5. Did the Subject Person cooperate with, and promptly respond to, all requests for information?

6. Did the Subject Person agree to a statute of limitations waiver or tolling agreement, if requested by OFAC (particularly in situations where the apparent violations were not immediately notified to or discovered by OFAC)?

H. Timing of apparent violation in relation to imposition of sanctions: The timing of the apparent violation in relation to the adoption of the applicable prohibitions, particularly if

the apparent violation took place soon after relevant changes in the sanctions program regulations or the addition of a new name to OFAC's List of Specially Designated Nationals and Blocked Persons (SDN List).

I. Other enforcement action: Other enforcement actions taken by federal, state, or local agencies against the Subject Person for the apparent violation or similar apparent violations, including whether the settlement of alleged violations of OFAC regulations is part of a comprehensive settlement with other federal, state, or local agencies.

J. Future Compliance/Deterrence Effect: The impact administrative action may have on promoting future compliance with U.S. economic sanctions by the Subject Person and similar Subject Persons, particularly those in the same industry sector.

K. Other relevant factors on a case-by-case basis: Such other factors that OFAC deems relevant on a case-by-case basis in determining the appropriate enforcement response and/or the amount of any civil monetary penalty. OFAC will consider the totality of the circumstances to ensure that its enforcement response is proportionate to the nature of the violation.

IV. Civil Penalties for Failure to Furnish Information or Keep Records

Except in the instance of authorized service providers under the Cuban Assets Control Regulations, for whom enforcement guidelines appear in the Service Provider Program Circular periodically issued by OFAC, as a general matter the following civil penalty amounts shall apply to a Subject Person's failure to furnish information or maintain records:

A. The failure to respond to a requirement to furnish information pursuant to 31 CFR 501.602, or failure to furnish the requested information, may result in a penalty in an amount up to \$20,000, irrespective of whether any other violation is alleged. Where OFAC has reason to believe that the apparent violation(s) that is the subject of the request to furnish information involves a transaction(s) valued at greater than \$500,000, a failure to respond to a request to furnish information or failure to furnish the requested information may result in a penalty in an amount up to \$50,000, irrespective of whether any other violation is alleged. A failure to respond to a requirement to furnish information or a failure to furnish the requested information shall be considered a continuing violation, and the penalties described above may be imposed each month that a party has continued to fail to respond or to furnish the requested information. OFAC may also seek to have a requirement to furnish information judicially enforced. Imposition of a civil monetary penalty for failure to respond to a requirement to furnish information or a failure to furnish the requested information does not preclude OFAC from seeking such judicial enforcement.

B. The late filing of a required report, whether set forth in regulations or in a specific license, may result in a civil monetary penalty in an amount up to \$2,500, if filed within the first 30 days after the report is due, and a penalty in an amount up

to \$5,000 if filed more than 30 days after the report is due. If the report relates to blocked assets, the penalty may include an additional \$1,000 for every 30 days that the report is overdue, up to five years.

C. The first failure to maintain records in conformance with the requirements of OFAC's regulations or of a specific license may result in a penalty in an amount up to \$5,000. Each additional violation in this regard may result in a penalty in an amount up to \$10,000.

V. Civil Penalties

OFAC will review the facts and circumstances surrounding an apparent violation and apply the General Factors for Taking Administrative Action in Section III above in determining whether to initiate a civil penalty proceeding and in determining the amount of any civil monetary penalty. OFAC will give careful consideration to the appropriateness of issuing a cautionary letter or finding of violation in lieu of the imposition of a civil monetary penalty.

A. Civil Penalty Process

1. *Pre-Penalty Notice.* If OFAC has reason to believe that a violation of U.S. sanctions has occurred and that a civil monetary penalty is warranted, it will issue a Pre-Penalty Notice in accordance with the procedures set forth in the particular regulations governing the conduct, activity, or transactions giving rise to the apparent violation. The amount of the proposed penalty set forth in the Pre-Penalty Notice will reflect OFAC's preliminary assessment of the appropriate penalty amount, based on information then in OFAC's possession. The amount of the final penalty may change as OFAC learns additional relevant information. If, after issuance of a Pre-Penalty Notice, OFAC determines that a penalty in an amount that represents an increase of more than 10 percent from the proposed penalty set forth in the Pre-Penalty Notice is appropriate, or if OFAC intends to allege additional violations, it will issue a revised Pre-Penalty Notice setting forth the new proposed penalty amount and/or alleged violations.

a. In general, the Pre-Penalty Notice will set forth the following with respect to the specific violations alleged and the proposed penalties:

- i. Description of the alleged violations, including the number of violations and their value, for which a penalty is being proposed;
- ii. Identification of the regulatory or other provisions alleged to have been violated;
- iii. Identification of the General Factors that were most relevant to the determination of the proposed penalty amount, including the base category (defined below) according to which the proposed penalty amount was calculated;
- iv. The maximum amount of the penalty to which the Subject Person could be subject under applicable law; and
- v. The proposed penalty amount, determined in accordance with the provisions set forth in these Guidelines.

b. The Pre-Penalty Notice will also include information regarding how to respond to the Pre-Penalty Notice including:

i. A statement that the Subject Person may submit a written response to the Pre-Penalty Notice by a date certain addressing the alleged violation(s), the General Factors Affecting Administrative Action set forth in Section III of these Guidelines, and any other information or evidence that the Subject Person deems relevant to OFAC's consideration.

ii. A statement that a failure to respond to the Pre-Penalty Notice likely will result in the imposition of a civil monetary penalty in the amount set forth in the Pre-Penalty Notice.

2. *Response to Pre-Penalty Notice.* A Subject Person may submit a written response to the Pre-Penalty Notice in accordance with the procedures set forth in the particular regulations governing the conduct, activity or transactions giving rise to the apparent violation. Generally, the response should either agree to the proposed penalty set forth in the Pre-Penalty Notice or set forth reasons why a penalty should not be imposed or, if imposed, why it should be a lesser amount than proposed, with particular attention paid to the General Factors Affecting Administrative Action set forth in Section III of these Guidelines. The response should include all documentary or other evidence available to the Subject Person that supports the arguments set forth in the response. OFAC will consider all relevant materials submitted.

3. *Penalty Notice.* If OFAC receives no response to a Pre-Penalty Notice within the time prescribed in the Pre-Penalty Notice, or if following the receipt of a response to a Pre-Penalty Notice and a review of the information and evidence contained therein OFAC concludes that a violation warranting a civil monetary penalty has occurred, a Penalty Notice generally will be issued in accordance with the procedures set forth in the particular regulations governing the conduct, activity or transactions giving rise to the violation. A Penalty Notice constitutes a final agency finding that a violation has occurred. The penalty amount set forth in the Penalty Notice will take into account relevant additional information provided in response to a Pre-Penalty Notice. In the absence of a response to a Pre-Penalty Notice, the penalty amount set forth in the Penalty Notice will generally be the same as the proposed penalty set forth in the Pre-Penalty Notice.

4. *Referral to Financial Management Division.* The imposition of a civil monetary penalty pursuant to a Penalty Notice creates a debt due the U.S. Government. OFAC will advise Treasury's Financial Management Division upon the imposition of a penalty. The Financial Management Division may take follow-up action to collect the penalty assessed if it is not paid within the prescribed time period set forth in the Penalty Notice. In addition or instead, the matter may be referred to the U.S. Department of Justice for appropriate action to recover the penalty.

5. *Final Agency Action.* The imposition of a penalty pursuant to a Penalty Notice constitutes final agency action with respect to the violation(s) for which the penalty is assessed.

B. Amount of Civil Penalty

1. *Egregious case.* In those cases in which a civil monetary penalty is deemed appropriate, OFAC will make a determination as to whether a case is deemed "egregious" for purposes of the base penalty calculation. This determination will be based on an analysis of the applicable General Factors. In making the egregiousness determination, OFAC generally will give substantial weight to General Factors A ("willful or reckless violation of law"), B ("awareness of conduct at issue"), C ("harm to sanctions program objectives") and D ("individual characteristics"), with particular emphasis on General Factors A and B. A case will be considered an "egregious case" where the analysis of the applicable General Factors, with a focus on those General Factors identified above, indicates that the case represents a particularly serious violation of the law calling for a strong enforcement response. A determination that a case is "egregious" will be made by the Director or Deputy Director.

2. *Pre-Penalty Notice.* The penalty amount proposed in a Pre-Penalty Notice shall generally be calculated as follows, except that neither the base amount nor the proposed penalty will exceed the applicable statutory maximum amount:

a. Base category calculation

i. In a non-egregious case, if the apparent violation is disclosed through a voluntary self-disclosure by the Subject Person, the base amount of the proposed civil penalty in the Pre-Penalty Notice shall be one-half of the transaction value, capped at a maximum base amount of \$125,000 per violation.

ii. In a non-egregious case, if the apparent violation comes to OFAC's attention by means other than a voluntary self-disclosure, the base amount of the proposed civil penalty in the Pre-Penalty Notice shall be the "applicable schedule amount," as defined above (capped at a maximum base amount of \$250,000 per violation).

iii. In an egregious case, if the apparent violation is disclosed through a voluntary self-disclosure by a Subject Person, the base amount of the proposed civil penalty in the Pre-Penalty Notice shall be one-half the statutory maximum penalty applicable to the violation.

iv. In an egregious case, if the apparent violation comes to OFAC's attention by means other than a voluntary self-disclosure, the base amount of the proposed civil monetary penalty in the Pre-Penalty Notice shall be the statutory maximum penalty amount applicable to the violation.

The following matrix represents the base amount of the proposed civil penalty for each category of violation:

Egregious Case

	NO	YES
YES	(1) One-Half of Transaction Value (capped at \$125,000 per violation)	(3) One-Half of Statutory Maximum
Voluntary Self-Disclosure	(2) Applicable Schedule Amount (capped at \$250,000 per violation)	(4) Statutory Maximum
NO		

The base penalty amount will not exceed the applicable statutory maximum amount.

b. Adjustment for applicable relevant General Factors

The base amount of the proposed civil penalty may be adjusted to reflect applicable General Factors for Administrative Action set forth in Section III of these Guidelines. Each factor may be considered mitigating or aggravating, resulting in a lower or higher proposed penalty amount. As a general matter, in those cases where the following General Factors are present, OFAC will adjust the base proposed penalty amount in the following manner:

i. In cases involving substantial cooperation with OFAC but no voluntary self-disclosure as defined herein, including cases in which an apparent violation is reported to OFAC by a third party but the Subject Person provides substantial additional information regarding the apparent violation and/or other related violations, the base penalty amount generally will be reduced between 25 and 40 percent. Substantial cooperation in cases involving voluntary self-disclosure may also be considered as a further mitigating factor.

ii. In cases involving a Subject Person's first violation, the base penalty amount generally will be reduced up to 25 percent. The extent of any such mitigation will be based, in part, on whether the Subject Person had previously been issued a cautionary, warning or evaluative letter.

In all cases, the proposed penalty amount will not exceed the applicable statutory maximum.

In cases involving a large number of apparent violations, where the transaction

value of all apparent violations is either unknown or would require a disproportionate allocation of resources to determine, OFAC may estimate or extrapolate the transaction value of the total universe of apparent violations in determining the amount of any proposed civil monetary penalty.

3. *Penalty Notice.* The amount of the proposed civil penalty in the Pre-Penalty Notice will be the presumptive starting point for calculation of the civil penalty amount in the Penalty Notice. OFAC may adjust the penalty amount in the Penalty Notice based on:

a. Evidence presented by the Subject Person in response to the Pre-Penalty Notice, or otherwise received by OFAC with respect to the underlying violation(s); and/or

b. Any modification resulting from further review and reconsideration by OFAC of the proposed civil monetary penalty in light of the General Factors for Administrative Action in Section III above.

In no event will the amount of the civil monetary penalty in the Penalty Notice exceed the proposed penalty set forth in the Pre-Penalty Notice by more than 10 percent, or include additional alleged violations, unless a revised Pre-Penalty Notice has first been sent to the Subject Person as set forth above. In the event that OFAC determines upon further review that no penalty is appropriate, it will so inform the Subject Person in a no-action letter, a cautionary letter, or a finding of violation.

C. Settlements

A settlement does not constitute a final agency determination that a violation has occurred.

1. *Settlement Process.* Settlement discussions may be initiated by OFAC, the Subject Person or the Subject Person's authorized representative. Settlements generally will be negotiated in accordance with the principles set forth in these Guidelines with respect to appropriate penalty amounts. OFAC may condition the entry into or continuation of settlement negotiations on the execution of a tolling agreement with respect to the statute of limitations.

2. *Settlement Prior to Issuance of Pre-Penalty Notice.* Where settlement discussions occur prior to the issuance of a Pre-Penalty Notice, the Subject Person may request in writing that OFAC withhold issuance of a Pre-Penalty Notice pending the conclusion of settlement discussions. OFAC will generally agree to such a request as long as settlement discussions are continuing in good faith and the statute of limitations is not at risk of expiring.

3. *Settlement Following Issuance of Pre-Penalty Notice.* If a matter is settled after a Pre-Penalty Notice has been issued, but before a final Penalty Notice is issued, OFAC will not make a final determination as to whether a sanctions violation has occurred. In the event no settlement is reached, the period specified for written response to the Pre-Penalty Notice remains in effect unless additional time is granted by OFAC.

4. *Settlements of Multiple Apparent Violations.* A settlement initiated for one apparent violation may also involve a

comprehensive or global settlement of multiple apparent violations covered by other Pre-Penalty Notices, apparent violations for which a Pre-Penalty Notice has not yet been issued by OFAC, or previously unknown apparent violations reported to OFAC during the pendency of an investigation of an apparent violation.

Dated: September 2, 2008.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. E8-20704 Filed 9-5-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2008-0290]

RIN 1625-AA00

Safety Zone; Gulf of Mexico—Johns Pass, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Johns Pass, Florida while construction operations are being conducted. This rule is necessary to ensure the safety of the workers and mariners on the navigable waters of the United States. No person or vessel may anchor, moor, or transit the Regulated Area without permission of the Captain of the Port St. Petersburg, Florida.

DATES: This safety zone will be effective August 29, 2008 through August 30, 2010.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2008-0290 and are available online at <http://www.regulations.gov>. This material is also available for inspection or copying at two locations: The Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays and Coast Guard Sector St Petersburg Prevention Department, 155 Columbia Dr., Tampa, FL 33606 between 7:30 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary

rule, call BM1 Charles Voss at Coast Guard Sector St. Petersburg, (813) 228-2191 Ext 8307. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On May 29, 2008 we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Gulf of Mexico—Johns Pass, FL in the **Federal Register**, 73 FR 30868. We did not receive any letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

Flatiron Construction will be performing construction work on the new Johns Pass Bridge. This work will involve setting girders, installing a new fendering system, setting the deck, setting overhangs, placing resteel, pouring the bridge deck, and wrecking the old bridge's deck. These operations will require the closure of the navigable channel. The closures will only be for limited times, during nighttime hours, and scheduled to accommodate the local marine traffic. The nature of the operation and environment surrounding the Johns Pass Bridge presents a danger to the workers and mariners transiting the area. This proposed safety zone is being established to ensure the safety of life on the navigable waters of the United States.

Discussion of Comments and Changes

No comments were received for this rule and no changes were made to the proposed rule text.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary.

The rule will only be enforced during a time when vessel traffic is expected to be minimal. Moreover, vessels may still enter the safety zone with the express

permission of the Captain of the Port St. Petersburg or a designated representative.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit Johns Pass, FL. This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will be enforced for a limited time when marine traffic is expected to be minimal; additionally traffic will be allowed to enter the zone with the permission of the Captain of the Port Sector St. Petersburg or a designated representative.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), in the NPRM, we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork